

2-21-06 07/044 086 C-0FC



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT NO. : 4,959,366  
APPLICATION NO. : 44,086  
ISSUE DATE : September 25, 1990  
INVENTORS : Cross, et al.

**RESUBMISSION OF REQUEST FOR CERTIFICATE OF CORRECTION**

ATTN: Certificate of Correction Branch  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Certificate  
FEB 24 2006  
of Correction

Sir:

Enclosed is a Request for Certificate of Correction (including the Certificate and Exhibits) for U.S. Patent No. 4,959,366. Applicants previously filed this Request for Certificate of Correction with the Office and are resubmitting the Request for Certificate of Correction at the instruction of the Office. The relevant facts are as follows:

- (1) On April 27, 2005, the Office issued a Certificate Extending Patent Term Under 35 U.S.C. § 156 for U.S. Patent No. 4,959,366 (the "Certificate Extending Patent Term").
- (2) The Certificate Extending Patent Term contained several errors as outlined in the attached Request for Certificate of Correction.
- (3) In May, 2005, the undersigned attorney contacted Karin Ferriter of the Patent Extension Branch regarding the errors in the Certificate Extending Patent Term. Ms. Ferriter instructed the undersigned to send the Request for Certificate of Correction to her by facsimile for filing, and indicated that she would forward the Request, along with the file to the Certificate of Correction Branch.
- (4) On June 1, 2005, the attached Request for Certificate of Correction was sent to Ms. Ferriter by facsimile. A copy of the facsimile confirmation report is attached.

FEB 28 2006

(5) In January, 2006, the undersigned attorney contacted the Certificate of Correction Branch to determine the status of the Request for Certificate of Correction and was advised that the Request for Certificate of Correction had not been received by the Certificate of Correction Branch. The individual with whom the undersigned spoke advised Applicant to resubmit the Request for Certificate of Correction to the Certificate of Correction Branch to ensure proper consideration thereof.

Accordingly, applicants are now re-submitting the previously filed Request for Certificate of Correction (including the Certificate and Exhibits) for U.S. Patent No. 4,959,366, and respectfully request issuance of a Certificate of Correction.

If the Office has any questions please contact the undersigned at the telephone number indicated.

Respectfully submitted,



Daniel S. Kasten

Registration No. 45,363

Telephone: 314-274-5218

Pharmacia Corporation of Pfizer Inc.  
P.O. Box 1027  
St. Louis, MO 63006





TRANSMISSION OK

\*\*\*\*\*  
\*\*\* TX REPORT \*\*\*  
\*\*\*\*\*



TX/RX NO 3623  
 CONNECTION TEL 915712737744  
 SUBADDRESS  
 CONNECTION ID  
 ST. TIME 06/01 14:33  
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 PGS. SENT 15  
 RESULT OK

**CERTIFICATE OF TRANSMISSION BY FACSIMILE (37 CFR 1.8)**

Applicant(s): Cross et al.

Docket No.

PCL428

Application No. 44,086 Patent# 4,959,336	Filing Date September 25, 1990	Examiner n/a	Group Art Unit n/a
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Invention: ANTI-ARRHYTHMIC AGENTS

I hereby certify that this Certificate of Correction; Request for Certificate of Correction; Exhibits A-H

(Identify type of correspondence)

is being facsimile transmitted to the United States Patent and Trademark Office (Fax. No. 571.273.7744)on June 1, 2005

(Date)

Linda K. Cooper

(Typed or Printed Name of Person Signing Certificate)

Note: Each paper must have its own certificate of mailing.

**CERTIFICATE OF TRANSMISSION BY FACSIMILE (37 CFR 1.8)**

Applicant(s): Cross et al.

Docket No.

PCL428

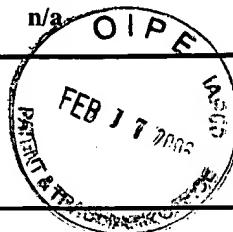
Application No.  
44,086 Patent# 4,959,336Filing Date P E  
September 23, 1990

Examiner

n/a

Group Art Unit  
n/a

Invention: ANTI-ARRHYTHMIC AGENTS

I hereby certify that this Certificate of Correction; Request for Certificate of Correction; Exhibits A-H  
(Identify type of correspondence)is being facsimile transmitted to the United States Patent and Trademark Office (Fax. No. 571.273.7744)on June 1, 2005  
(Date)Linda K. Cooper

(Typed or Printed Name of Person Signing Certificate)



The signature is handwritten in cursive ink and reads "Linda K. Cooper". Below the name, the words "(Signature)" are written in parentheses. To the right of the name, there is a handwritten note "15 pages enc".

Note: Each paper must have its own certificate of mailing.

# UNITED STATES PATENT AND TRADEMARK OFFICE

## CERTIFICATE OF CORRECTION

PATENT NO : 4,959,366

DATED : September 25, 1990

INVENTOR(S) : Cross et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Certificate Extending Patent Term Under 35 U.S.C. § 156, issued April 27, 2005:

(a) in the heading of the Certificate, following [(45) ISSUED], "May 25, 1990" should read --September 25, 1990--.

(b) in the heading of the Certificate, following [(95) PRODUCT], "TIKOSYN® (methanesulfonamide)" should read --TIKOSYN® (dofetilide)--.

(c) at lines 3-4 of the first paragraph of the text of the Certificate, "TIKOSYN® (methanesulfonamide)" should read --TIKOSYN® (dofetilide)--.

MAILING ADDRESS OF SENDER: Daniel S. Kasten  
P.O. Box 1027  
Chesterfield, Missouri 63006

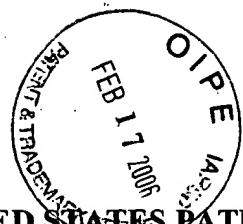
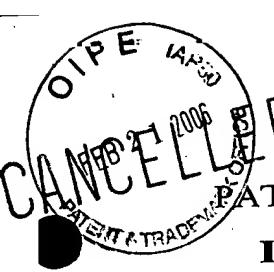
PATENT NO. 4,959,336

No. of additional copies



This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing the burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT NO. : 4,959,366  
APPLICATION NO. : 44,086  
ISSUE DATE : September 25, 1990  
INVENTORS : Cross, et al.

**REQUEST FOR CERTIFICATE OF CORRECTION**

ATTN: Certificate of Correction Branch  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicant requests the Office to issue a Certificate of Correction pursuant to 37 C.F.R. 1.322 for U.S. Patent 4,959,366. Specifically, Applicant requests the Office to correct the Certificate Extending Patent Term Under 35 U.S.C. § 156 issued April 27, 2005, for U.S. Patent 4,959,366. The requested corrections are identified in the attached Certificate of Correction Form PTO/SB/44.

Applicant believes that the errors to be corrected are attributable solely to the Office and requests expedited processing and grant of the Certificate of Correction. If the Office disagrees and believes that one or more of the errors are attributable to Applicant, the Office may instead treat this request as one for the Office to issue a Certificate of Correction pursuant to 37 C.F.R. 1.323 for U.S. Patent 4,959,366.

The specific facts related to the requested corrections are set forth below:

- (1) The heading of the Certificate Extending Patent Term lists the incorrect issue date for U.S. Patent 4,959,366. The correct issue date is clearly reflected on the face of U.S. Patent 4,959,366. Applicant is not aware of any prior occurrences of this error. Thus, it appears that the error is of a

clerical nature, and attributable solely to the Office. A copy of the face sheet of the '366 patent is attached as Exhibit A.

- (2) The remaining two errors in the Certificate Extending Patent Term are references to the product as "TIKOSYN® (methanesulfonamide)" rather than as "TIKOSYN® (dofetilide)".
- (3) The active ingredient in TIKOSYN® is *N*-[4-[2-[methyl][2-[4-[(methylsulfonyl)amino]phenoxy]ethyl]amino]ethyl]phenyl]-methanesulfonamide. Dofetilide is the U.S. Adopted Name and the International Nonproprietary Name for this compound. On November 18, 1999, Applicant submitted an application for extension of the term of U.S. Patent 4,959,366 under 35 U.S.C. § 156. The application for extension referred to the approved product "TIKOSYN® (dofetilide)". A copy of the first page of the application is attached as Exhibit B.
- (4) By letter to the Food and Drug Administration ("FDA") on or about December 1, 1999, the Office requested FDA to confirm "that the product identified in the application, TIKOSYN® (dofetilide), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved." A copy of this letter is attached as Exhibit C.
- (5) By letter to the Office on or about April 26, 2000, the FDA confirmed that the product had been subject to a regulatory review period and that the subsequent marketing and use represented the first commercial marketing or use of that product. The FDA further confirmed that the application for patent term extension was timely filed. Although this letter listed the correct product trade name (TIKOSYN®), New Drug Application (NDA No. 20-931) and patent (U.S. Patent 4,959,366), the generic name listed for the product was incorrect (methanesulfonamide rather than dofetilide). A copy of this letter is attached as Exhibit D.
- (6) By letter to the Office on or about November 17, 2003, the FDA indicated that it had published its determination of the product's regulatory review

period and that it considered the regulatory review period determination to be final. This letter listed the correct product trade name (TIKOSYN®), New Drug Application (NDA No. 20-931) and patent (U.S. Patent 4,959,366), but the generic name listed for the product was incorrect (methanesulfonamide rather than dofetilide). A copy of this letter is attached as Exhibit E.

- (7) On January 25, 2005, the Office issued a Notice of Final Determination stating that U.S. Patent No. 4,959,366 was entitled to a five-year extension of term through September 25, 2012. Although the Notice of Final Determination listed the correct patent (U.S. Patent 4,959,366) and product trade name (TIKOSYN®), the generic name for the product was listed incorrectly three times (methanesulfonamide rather than dofetilide). A copy of the Notice of Final Determination is attached as Exhibit F.
- (8) On January 26, 2005, Applicant filed a letter stating that Pfizer Inc, the owner of record of U.S. Patent No. 4,959,366, did not wish to file a request for reconsideration of the final determination as to the length of extension of the term of that patent. This letter did not expressly comment on the incorrect references to the generic name (methanesulfonamide rather than dofetilide) contained in the Notice of Final Determination. A copy of this letter is attached as Exhibit G.
- (9) On April 27, 2005, the Office issued a Certificate Extending Patent Term Under 35 U.S.C. § 156 for U.S. Patent 4,959,366. Although the Certificate Extending Patent Term listed the correct patent (U.S. Patent 4,959,366) and product trade name (TIKOSYN®), the generic name for the product was listed incorrectly two times (methanesulfonamide rather than dofetilide). A copy of the Certificate Extending Patent Term is attached as Exhibit H.

Accordingly, Applicant respectfully requests expedited handling and grant of a Certificate of Correction pursuant to 37 C.F.R. 1.322 for U.S. Patent 4,959,366. In the event the Office believes, however, that one or more of the

FEB 28 2006

errors to be corrected are attributable to Applicant, Applicant respectfully requests the Office instead to treat this request as one for issuance of a Certificate of Correction pursuant to 37 C.F.R. 1.323 for U.S. Patent 4,959,366. The Office is hereby authorized to charge any fees that may be required in this matter to Deposit Account No. 19-1025.

Respectfully submitted,



Daniel S. Kasten

Registration No. 45,363

Telephone: 314-274-5218

Pharmacia Corporation of Pfizer Inc.  
P.O. Box 1027  
Chesterfield, Missouri 63006

# United States Patent [19]

Cross et al.

[11] Patent Number: 4,959,366

[45] Date of Patent: Sep. 25, 1990

[54] ANTI-ARRHYTHMIC AGENTS

[75] Inventors: Peter E. Cross, Geoffrey N. Thomas,  
John E. Arrowsmith, all of New  
York, N.Y.

[73] Assignee: Pfizer Inc., New York, N.Y.

[21] Appl. No.: 44,086

[22] Filed: Apr. 29, 1987

[30] Foreign Application Priority Data

May 1, 1986 [GB] United Kingdom ..... 8610668  
Dec. 17, 1986 [IE] Ireland ..... 8630059

[51] Int. Cl' C07C 143/75; C07C 93/06

[52] U.S. Cl ..... 514/239.5; 514/255;  
514/315; 514/410; 514/605; 514/618; 514/619;  
514/620; 514/621; 514/649; 514/651; 514/654;  
544/165; 544/167; 544/399; 546/226; 546/539;  
564/99; 564/162; 564/164; 564/166; 564/336;  
564/341; 564/348; 564/354

[58] Field of Search ..... 564/99, 336, 341, 348,  
564/354, 162, 164, 166; 514/605, 821, 239.5,  
255, 315, 410, 618, 619, 620, 621; 546/226;  
548/539; 544/399, 165, 167

[56] References Cited

U.S. PATENT DOCUMENTS

3,341,584 9/1967 Larsen et al. ..... 260/556

3,478,149 11/1969 Larsen et al. ..... 424/228  
3,574,741 4/1971 Gould et al. ..... 260/556  
3,660,487 5/1972 Larsen et al. ..... 260/556  
3,758,692 9/1973 Larsen et al. ..... 424/321  
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4,396,627 8/1983 Ainsworth et al. ..... 564/99  
4,478,849 10/1984 Ainsworth et al. ..... 564/99

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0164865 12/1985 European Pat. Off. ..... 514/605  
977261 7/1966 France ..... 514/605  
1263987 2/1972 United Kingdom ..... 514/605  
1301134 12/1982 United Kingdom ..... 514/605  
2135883 9/1984 United Kingdom ..... 514/605

OTHER PUBLICATIONS

Larsen et al., "Sulfonanilides, II: Analogs of Catecholamines", J. Am. Chem. Soc. 75, 4334 (1953).

Primary Examiner—Richard L. Raymond  
Assistant Examiner—Raymond Covington  
Attorney, Agent, or Firm—Peter C. Richardson; Paul H. Ginsburg; Robert F. Sheyka

[57] ABSTRACT

A series of [N-alkyl-N-(nitro-, alkylsulphonamido, or amino-phenalkyl)amino]-alkyl, alkoxy or alkylthio phenyl derivatives having utility as anti-arrhythmic agents.

48 Claims, No Drawings

Exhibit A



PC7068AADO

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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IN RE: U.S. Patent No. 4,959,366:  
ISSUED: September 25, 1990 :  
TO: Peter E. Cross, et al. :  
FOR: Anti-Arrhythmic Agents :  
FROM: Serial No. 44,086 :  
FILED: APRIL 29, 1987 :  
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BOX PATENT EXTENSION  
Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Your applicant, Pfizer Inc. ("PFIZER"), a corporation of the State of Delaware and having a place of business at 235 East 42nd Street, New York, New York, represents that it is the legal owner of record of Letters Patent of the United States No. 4,959,366, granted to Peter E. Cross, Geoffrey N. Thomas and John E. Arrowsmith<sup>1</sup> on the twenty-fifth day of September, 1990, for Anti-Arrhythmic Agents, by virtue of an assignment, recorded in the United States Patent and Trademark Office on the twenty-ninth day of April, 1987, at Reel 4780, Frame 0801; that Pfizer Pharmaceuticals Production Corporation Limited ("PPPCL") is an indirectly-owned subsidiary of PFIZER; that PFIZER controls, indirectly, all the voting shares of PPPCL; that PPPCL is the owner of New Drug Application ("NDA") No. 20-931 for TIKOSYN (dofetilide), claimed by U.S. Patent No. 4,959,366; and that PFIZER is entitled to rely on the marketing approval for TIKOSYN (dofetilide) arising from NDA No. 20-931.

<sup>1</sup> Subsequently, a certificate of correction (Exhibit B) dated May 11, 1999 certified that the correct inventorship is: Peter E. Cross and Geoffrey N. Thomas.

DEC - 1 1999



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office  
ASSISTANT SECRETARY AND COMMISSIONER  
OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

DC 7063ARFS

David T. Read  
Acting Director Regulatory Policy Staff, CDER  
Food and Drug Administration  
1451 Rockville Pike, HFD-7  
Rockville, MD 20852

Dear Mr. Read:

The attached application for patent term extension of U.S. Patent No. 4,959,366 was filed on November 19, 1999, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, TIKOSYN (dofetilide), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product, or the method of use of manufacturing such a product, which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)308-6916 (facsimile).

*Karin Tyson*  
Karin Tyson \_\_\_\_\_  
Legal Advisor  
Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Gregg C. Benson  
Pfizer Inc.  
Patent Department  
Eastern Point Road  
Groton CT 06340

kt

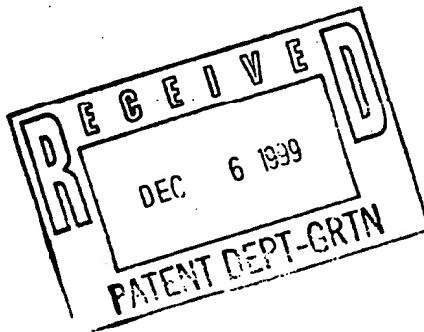


Exhibit C



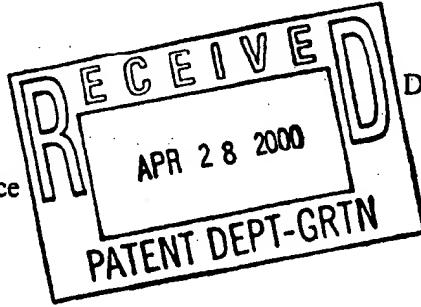
## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

APR 26 2000

The Honorable Q. Todd Dickinson  
Director of U.S. Patent and Trademark Office  
Commissioner for Patents  
Box Pat. Ext.  
Washington, D.C. 20231

Re: Tikosyn®  
Docket No. 00N-1248

Dear Director Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 4,959,366 filed by Pfizer under 35 U.S.C. § 156. The human drug product claimed by the patent is Tikosyn® (methanesulfonamide), which was assigned new drug application (NDA) No. 20-931.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in *Glaxo Operations UK Ltd. v. Quigg*, 706 F. Supp. 1224 (E.D. Va. 1989), *aff'd*, 894 F. 2d 392 (Fed. Cir. 1990).

The NDA was approved on October 1, 1999, which makes the submission of the patent term extension application on November 19, 1999, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

cc: Gregg C. Benson  
Pfizer, Inc.  
Patent Department  
Eastern Point Rd  
Groton, CT 06340

Exhibit D



DEPARTMENT OF HEALTH & HUMAN SERVICES

HC0070USA RAP

Public Health Service  
Former # PLC 428

Food and Drug Administration  
Rockville MD 20857

Re: Tikosyn  
Docket No. 00N-1248

The Honorable James E. Rogan  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office  
Box Pat. Ext.  
P.O. Box 1450  
Alexandria, VA 22313-1450

NOV 17 2003

Dear Director Rogan:

This is in regard to the patent term extension application for U.S. Patent No. 4,959,366 filed by Pfizer under 35 U.S.C. § 156. The patent claims Tikosyn (methanesulfonamide), NDA 20-931.

In the April 18, 2003, issue of the Federal Register (68 Fed. Reg. 19212), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before October 15, 2003, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

*Jane A. Axelrad*

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

cc: Gregg C. Benson  
Pfizer, Inc.  
Patent Department  
Eastern Point Rd.  
Groton, CT 06340

**RECEIVED**

JAN 21 2004

PHARMACIA  
GLOBAL PATENT DEPT.  
ST. LOUIS, MO

Exhibit E

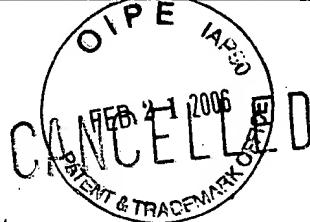


UNITED STATES PATENT AND TRADEMARK OFFICE



Commissioner for Patents  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

Gregg C. Benson  
Pfizer, Inc.  
Patent Department  
Eastern Point Road  
Groton CT 06340



Mailed: January 25, 2005

Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,959,366

### NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,959,366, which claims the human drug product TIKOSYN® (methanesulfonamide) and a method of use of said product, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be five years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of five years.

Under 35 U.S.C. § 156(c), the period of extension is calculated using the Food and Drug Administration's determination of the length of the regulatory review period as published in the Federal Register of April 18, 2003 (68 Fed. Reg. 19212).

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2}(2,778 - 56) + 572 \\ &= 1,933 \text{ days}\end{aligned}$$

Since the regulatory review period began August 1, 1990, before the patent issue date (September 25, 1990), the period during the regulatory review period on or before the issue date of the patent has been subtracted from the "testing phase" in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

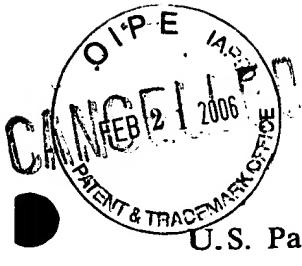
The five year limitation of 35 U.S.C. § 156(g)(6)(A) applies in the present situation, however, because the patent was issued after the date of enactment (September 24, 1984) of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) cannot exceed five years under 35 U.S.C. § 156(g)(6)(A), the period of extension will be for five years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,959,366
Granted:	September 25, 1990
Original Expiration Date <sup>1</sup> :	September 25, 2007
Applicant:	Cross, et al.

<sup>1</sup>Subject to the provisions of 35 U.S.C. § 41(b).



U.S. Patent No. 4,959,366



Page 2

Owner of Record: Pfizer Inc.  
Title: ANTI-ARRHYTHMIC AGENTS  
Classification: 514/239.5  
Product Trade Name: TIKOSYN® (methanesulfonamide)  
Term Extended: Five years  
Expiration Date of Extension: September 25, 2012

Any correspondence with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents  
Mail Stop Patent Ext.  
P.O. Box 1450  
Alexandria, VA 22313-1450

By FAX: (703) 273-7744  
Attn: Office of Patent Legal Administration

Telephone inquiries related to this determination should be directed to the undersigned at 571-272-7744.

---

Karin Ferriter  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Office of Regulatory Policy  
HFD - 13  
5600 Fishers Lane  
Rockville, MD 20857

Attention: Claudia Grillo

RE: TIKOSYN® (methanesulfonamide)  
FDA Docket No.: 00N-1248

100-28-4662

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**



**IN RE:** U.S. Patent No. 4,959,366 :  
**ISSUED:** September 25, 1990 :  
**TO:** Peter E. Cross, et al. :  
**FOR:** Anti-Arrhythmic Agents :  
**FROM:** Application Ser. No. 44,086 :  
**FILED:** April 29, 1987

Commissioner for Patents  
Mail Stop Patent Extension  
P.O. Box 1450  
Alexandria, VA 22313-1450

**LETTER RE: CERTIFICATE OF EXTENSION**

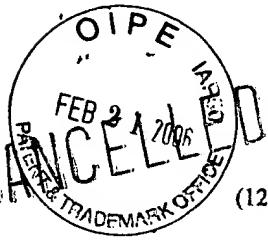
Sir:

Further to the Notice of Final Determination, dated January 25, 2005, Pfizer Inc., the Owner of Record of U.S. Patent No. 4,959,366, does NOT wish to file a request for reconsideration of the final determination as to the length of extension of the term of that patent. Accordingly, Pfizer Inc. respectfully requests that the Certificate of Extension be issued as soon as possible.

Respectfully submitted,

Daniel S. Kasten  
Patent Counsel  
Reg. No. 45,363  
Tel: 314-274-5218

Pfizer Inc.  
Patent Department  
575 Maryville Centre Drive  
St. Louis, MO 63141



UNITED STATES PATENT AND TRADEMARK OFFICE

(12)

CERTIFICATE EXTENDING PATENT TERM  
UNDER 35 U.S.C. § 156

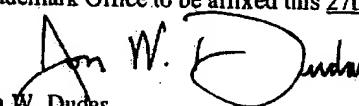
(68) PATENT NO. : 4,959,366  
(45) ISSUED : May 25, 1990  
(75) INVENTOR : Cross, et al.  
(73) PATENT OWNER : Pfizer Inc.  
(95) PRODUCT : TIKOSYN® (methanesulfonamide)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 4,959,366 based upon the regulatory review of the product TIKOSYN® (methanesulfonamide) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94) Five Years

from September 25, 2007, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).

I have caused the seal of the United States Patent and  
Trademark Office to be affixed this 27th day of April 2005.

  
Jon W. Dudas  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office

FEB 28 2006

Exhibit H

BEST AVAILABLE COPY

**CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)**

Applicant(s): Cross et al.

Docket No.

PCL428

Application No. 44,086 Patent 4,959,336	Filing Date September 25, 1990	Examiner n/a	Customer No. 26648	Group Art Unit n/a
Invention: Anti-Arrhythmic Agents				

*O I P E*  
*U N C E L L E D*  
*U. S. P T O - M A R K I N G & T R A C K I N G S Y S T E M*

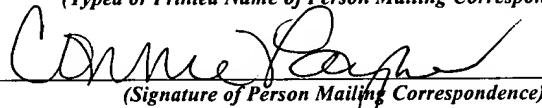
*O I P E*  
*F E B 1 7 2006*  
*U. S. P T O - M A R K I N G & T R A C K I N G S Y S T E M*

I hereby certify that the following correspondence:

**Resubmission of Request for Cert. of Correction, Facsimile Transmission Receipt, Certificate of Transmission by Facsimile, Certificate of Correction, Request for Certificate of Correction (4pgs), Exhibit A, Exhibit B, Exhibit C, Exhibit D, Exhibit E, Exhibit F, Exhibit G, Exhibit H and return receipt postcard**

*(Identify type of correspondence)*

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

February 17, 2006*(Date)*Connie Payne*(Typed or Printed Name of Person Mailing Correspondence)**(Signature of Person Mailing Correspondence)*EV846966026 US*("Express Mail" Mailing Label Number)*

Note: Each paper must have its own certificate of mailing.